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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1632

DATE MAILED: 07/03/2002

(D)

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/462,955

Applicant(s)

ROHDE ET AL.

Examiner

Eleanor Sorbello

Art Unit

1632

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 02 April 2002.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 11-25 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 11-25 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) All    b) Some \* c) None of:

        1. Certified copies of the priority documents have been received.

        2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

        3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    \* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

    a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_      6) Other: \_\_\_\_\_

***Response to amendment***

1. Applicant's amendment filed 4/2/02, paper number 12 has been entered. Claims 12-21 have been amended, and claims 23-25 have been added. **Claims 11-25 are pending.** Applicant's amendments and arguments have been thoroughly reviewed, but are persuasive only to a point for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's argument.
2. Applicant's arguments are addressed below on a per section basis. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Specification***

3. The abstract of the disclosure is objected to because the specification at page 3, line 13, reciting claim 1, should be replaced with the text of the original claim 1. Correction is required. See MPEP § 608.01(b).

***Claim Objections***

4. Claim 12 is objected to because SEQ. ID. NO: 2 is not infact the stem loop structure of SEQ. ID. NO: 1, but is the complement of the stem loop structure of SEQ. ID. NO: 1.
5. Claim 17 is objected to because of the phrase "transfected a cell one or more DNA fragments". It is suggested that this phrase be amended to read, "transfected a cell with one or more DNA fragments".

6. Claim 18 is objected to because of the phrase "cell is a bacteria, yeast[s] or fungi cell". It is suggested that this phrase be amended to read, "cell is a bacterial, yeast or fungal cell".

7. Claim 23 is objected to because of the phrase "virus virus". It is suggested that one "virus" be deleted.

8. NOTE: It is to be noted also that the clean and marked up versions of claim 3, amended in the amendment B, dated 9/26/01 (which has since been renumbered claim 14) differed from that of claim 3 presented in the preliminary amendment A.

9. Applicants are not required to supply a certified copy of the German Priority document. The file contains the WIPO stamped document and the translation of the German Priority document.

10. The amendment filed 9/26/01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is described below:

Applicant is required to cancel the new matter in the reply to this Office Action.

Applicants have attempted to include SEQ. ID. NO: 1 (Rohde, Virology 176: 648-651, 1990) into the specification which was not described in the original disclosure. The specification does not indicate that Rohde, Virology 176: 648-651, 1990, was to be

incorporated by reference. In order for SEQ ID NO: 1 to be incorporated into the specification, without introducing new matter, applicant must provide an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

#### Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 11, 13, 15, 16, 17-21, 24, 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 13, 15, 24, are rejected under 35 U.S.C. 112 second paragraph because there is insufficient antecedent basis for "DNA fragment according to claim 1". There is no claim 1.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of the phrase "conserved variants" are not defined in the specification. It is unclear how different from SEQ. ID. NO: 1(or a fragment of SEQ. ID. NO: 1) the "DNA fragment" can be to be a "conserved variant".

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, for reciting "a modified promoter which does not have an activity 20% more than or 20% less than the promoter activity of nucleotides 211-991 of SEQ. ID. NO: 1", which is unclear. As shown by comparing Table 2 with Table 3, the relative promoter activity varies depending on the assay used. In tobacco, only the fragment 211-911 meets the limitation. However, in E. coli, the following fragments: 211-991, 409-991, 711-991 meet this limitation.

Claims 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The claims are directed to a method of expressing a nucleic acid, yet the steps do not involve "a nucleic acid" that can be expressed, only a promoter. The "fragments" of claim 12 are only CFDV fragments.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 makes no sense. It is unclear how transfecting a cell relate to making a construct? The body of the claim does not relate back to the preamble.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph because it depends from itself, claim 25. Thus it is unclear what the metes and bounds of the claim are.

13. Claims 12, 13, 17-21, 23 are rejected under 35 USC § 112, first paragraph  
because the specification, while being enabling for a CFDV virus fragment of at least nucleotides comprising position 711-991 of SEQ. ID. NO: 1, which has promoter activity, **does not** reasonably provide enablement for a CFDV virus fragment that has promoter activity that only has the stem-loop structure set forth in nucleotides 962-991 of SEQ. ID. NO: 1.

Claims 11, 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification conflicts with the publications by Rohde et. al (see Virology, 1990, 176, 648-651) and Hehn, (Journal of General Virology, 1998, 79, 1495-1499) as to the exact nucleotides of SEQ. ID. NO: 1, that are absolutely required for promoter function. The claims recite that the stem loop structure is required for promoter activity. The claims recite that the stem loop structure and an additional region as interpreted by the claim language reciting "comprising", which has not been specifically identified in the claims. Rohde et al. (1990) teaches that while the stem-loop enhances promoter activity, it is not required for activity. Rohde et al. (Plant Molecular Biology, 27: 623-628, 1995), see page 625, col. 2, paragraph 2, teaches that the 52bp stretch is required for promoter activity, and if that stretch of nucleotides is removed, then activity is abolished. Therefore, the stem loop structure alone does not confer activity on the

promoter. Applicants base claim only requires the stem loop and does not identify that a specific region, other than the stem loop, which may be the 52 bp region Apa L1/Nar I fragment, is absolutely necessary for increased promoter activity. Hehn's reference teaches that no activity was found in promoter pRTCF27 (see page 1496, col. 2, paragraph 1). See Fig. 1 page 1495 of Hehn that teaches that CF27 comprises the stem loop structure and the TATA box, but not the 52 base pair region. Therefore, it is apparent that the stem loop structure alone does not have promoter function. The smallest fragment shown to have activity in the specification was the 711-991 fragment, which includes the 52 bp region.

Regarding claim 16, drawn to making conserved variants of SEQ. ID. 1 or any fragment which does not have 20% more promoter function or 20% less promoter function than nucleotides 211-911 of SEQ. ID. NO: 1, applicants are not enabled for reasons discussed herein. If one compares the promoter functions of pRT CF2 as seen in Table 2, of the specification with that of all other fragments disclosed, only pRTCF2 meets the limitation of the claims. It is to be noted that 20% is within the experimental error seen in the trials conducted. The specification provides no guidance on altering SEQ. ID. NO: 1, rather than deleting all but nucleotides 211-991 of SEQ. ID. NO: 1, that would result in activity that was within 20% of that observed for the 211-991 fragment, when measured in tobacco protoplasts. Therefore, the specification does not support making and using conserved variants of the promoter that comprises nucleotides 211-911 of SEQ. ID. NO: 1 and one of skill will therefore require undue experimentation to make and use the invention as claimed.

Claims 11 and 22 are directed to transgenic plants, parts of plants and transformed plants none of which have been supported by the disclosure. The specification merely contemplates transgenic plants. It provides no guidance for making and using them an no working examples.

Therefore, the above factors when considered, does not provide for enablement. Since the CFDV promoter is a novel promoter the amount of guidance set forth as regards variants of the CFDV promoter is lacking; the breadth of the claims, which reads on conserved variants of the CFDV promoter that has an activity of not more than or less than 20% of the promoter activity of nucleotides 211-911 of SEQ. ID. NO: 1; the lack of predictability of performance of conserved the variants of the CFDV promoter and the state of the art does not enable one skilled in the art to which it pertains to make and use the invention as claimed.

In conclusion, given the nature of the invention, the state of the art, the demonstrated lack of predictability of the art, the amount of guidance set forth, the breadth of the claims, and the lack of working examples, one of skill in the art could not make and use the invention without undue experimentation.

14. Claims 16, 22 are rejected under 112 first paragraph as containing subject matter for lacking written description.

Claim 16 is directed to a conserved variant of SEQ. ID. NO: 1 or a fragment thereof, which is a modified promoter which does not have an activity 20% more or 20% less than the promoter activity of nucleotides 211-991 of SEQ. ID. NO: 1.

Applicants have not described what these conserved variants are, and as such are only in possession of a DNA fragment comprising nucleotides 211-991 of SEQ. ID. NO: 1, but not the full breadth of the claim.

Applicants have not described any mutations that have been made which have the activity which is not more or less than 20% of the SEQ. ID. NO: 1 fragment of nucleotides 211-991, and what structure function relationship there is. The specification does not teach one how to distinguish fragments that would have this activity by a specific structure. The specification does not describe what structural features must be present in the variant to meet the limits on activity other than consisting of nucleotides 211-991 of SEQ. ID. NO: 1. Table 2 shows that even removing or adding CFDV sequences to 211-991 unpredictably alter promoter activity.

Applicants state that claims 11-22 were rejected for lacking written description. However, as stated above, only claims 12 and 16 were rejected for lacking written description in the previous office action dated 11/27/01.

### ***Claim Rejections - 35 USC § 102***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 16, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhode.( Plant Molecular Biology, 27: 623-628, 1995).

Rhode teaches a CFDV (Xhol-Sty I) fragment comprising a stem loop structure, but not ORF-2, translation start site, see Fig. 1A.

With respect to claim 16, instant table 3, shows that in E. coli, the Xhol-Sty I fragment (pRTCFXS) has promoter activity that is within 20% of that seen for the 211-991 fragment.

Therefore, all elements of the claims were anticipated by Rohde.

#### ***Double Patenting***

17. Claims 11-22 remain rejected and claims 23-25 are rejected under the judicially created doctrine of obviousness type double patenting. When applicants submit a Terminal Disclaimer, this rejection will be dropped.

#### ***Conclusion***

18. Claims 11-22 remain rejected and 23-25 are rejected.

19. Any inquiry concerning this communication should be directed to Eleanor Sorbello, who can be reached at (703)-308-6043. The examiner can normally be reached on Mondays-Fridays from 6.30 a.m. to 3.00 p.m. EST.

Questions of formal matters can be directed to the patent analyst, Patsy Zimmerman, whose telephone number is (703) 308-0009.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone

number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

If the claims are amended canceled and/or added the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED to facilitate further examination.

Eleanor Sorbello

*Scott D. Priebe*

SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER